EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF NORTHWEST KIDNEY CENTERS PROPOSING TO ADD SIX DIALYSIS STATIONS TO THE EXISTING TWENTY-TWO STATION FACILITY KNOWN AS MOUNT RAINIER KIDNEY CENTER

PROJECT DESCRIPTION

Northwest Kidney Centers (NKC) located in Seattle Washington is a private, not-for-profit corporation, incorporated in the state of Washington. NKC was established in 1962 and operates eleven kidney dialysis treatment facilities in King County[1] and one facility in Clallam County.[2] [source: CN historical files]

One of the facilities owned and operated in King County is the dialysis facility known as Mount Rainier Kidney Center (MRKC). MRKC began operations in 1986 and is currently located at 4242 East Valley Road in the city of Renton. This application proposes to add six dialysis stations to the existing 22 stations for a total of 28 dialysis stations in operation at MRKC. Types of patients that receive services at MRKC include:

- stable hemodialysis patients who are unable or unwilling to dialyze at home;
- home hemodialysis patients who require occasional facility backup treatments;
- visiting hemodialysis patients; and
- stable hospitalized hemodialysis patients transported for outpatient treatments.
  [source: Application, pp4, 15]

The estimated capital expenditure to add the six dialysis stations is $74,926, of which 67% is related to construction, 26% is related to equipment (both fixed and moveable) and the remaining 7% is related to sales tax. [source: Application, p13]

NKC anticipates commencement of this project by March 1, 2006 and completion by June 30, 2006. The first full year of operation as a 24-station facility is year 2007. [source: Application, p17]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the increase in the number of dialysis stations at an existing kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105 (4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

APPLICATION CHRONOLOGY

May 9, 2005	Letter of Intent Submitted
August 1, 2005	Application Submitted

[1] Haviland Kidney Center, Auburn Kidney Center, Cascade Kidney Center, Elliott Bay Kidney Center, Lake City Kidney Center, Lake Washington Kidney Center, Scribner Kidney Center, Snoqualmie Ridge Kidney Center, Mt. Rainier Kidney Center, Totem Lake Kidney Center, and West Seattle Kidney Center.
[2] Port Angeles Kidney Center.

APPLICATION CHRONOLOGY (continued)

August 1, 2005 through	Department's Pre-Review Activities
August 25, 2005	• 1st screening activities and responses
August 25, 2005	Department Begins Review of the Application
	• public comments accepted throughout review
October 24, 2005	Public Hearing Conducted in Renton
October 24, 2005	End of Public Comment
November 9, 2005	Rebuttal Documents Submitted to the Department
December 26, 2005	Department's Anticipated Decision Date
February 14, 2006	Department's Actual Decision Date

AFFECTED PARTIES

Throughout the review of this project, one entity--DaVita Inc.--sought and received affected person status under WAC 246-310-010.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers' Certificate of Need Application dated July 29, 2005
- Northwest Kidney Centers' supplemental information dated August 19 and August 29, 2005
- Comments provided by DaVita, Inc. dated October 24, 2005
- Rebuttal comments provided by Northwest Kidney Centers dated November 7, 2005
- Rebuttal comments provided by DaVita, Inc. received November 9, 2005
- DaVita, Inc. October 19, 2005 responses to the department's patient zip code data request
- Historical kidney dialysis data obtained from the Northwest Renal Network[3]
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Data obtained from Center for Medicare and Medicaid (CMS) "Dialysis Facility Compare" website (http://www.medicare.gov/Dialysis/home.asp).
- Data obtained from the Internet regarding health care providers
- Population data obtained from the Office of Financial Management
- Mapping data obtained from the Department of Health's Division of Information Resource Management
- Data obtained from the Internet regarding mileage and distance
- Certificate of Need historical files

[3] Northwest Renal Network (NRN) was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, individual unit, or transplant center. NRN is funded by the Centers for Medicare & Medicaid Services, Department of Health and Human Services, and collects and analyzes data on patients enrolled in the Medicare end stage renal disease (ESRD) program. NRN serves as an information resource, and monitors the quality of care provided to dialysis and transplant patients in the Pacific Northwest. [source: NRN home page]

CRITERIA EVALUATION

To obtain Certificate of Need approval, Northwest Kidney Centers must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment); and 246-310-280 (the dialysis station projection methodology and standards).[4]

CONCLUSION

For the reasons stated in this evaluation, the application submitted by on behalf of Northwest Kidney Centers proposing to add six stations to Mount Rainier Kidney Center is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need should not be issued.

[4] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-240(2) and (3).

A. Need (WAC 246-310-210)

Based on the source information reviewed the department determines that the applicant has not met the need criteria in WAC 246-310-210(1) and (2) and WAC 246-310-280.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

The Department of Health's Certificate of Need Program uses the methodology found in WAC 246-310-280 for projecting numeric need for dialysis stations within a county. Using verified facility utilization information for King County for the years 1999 through 2004, the department projects the need for dialysis stations to serve the county. In recent evaluations, the department has evaluated need by examining both linear and non-linear projections of the data. One measure of the accuracy of a regression equation is the determinant of regression, or R^2. R^2 is a value that describes the relation of actual data to the expected values based on the regression analysis of that data. In general, the closer an equation's R^2 value is to one, the more reliable a regression equation is perceived to be. The department concludes that each value to be estimated should be evaluated using both linear and non-linear regression methods and the regression equation deemed more reliable should be used to predict that data element. In some cases, this will be the non-linear equation; in others, the data may be better described by a linear equation. This approach is referenced in this document as "best fit." For those values with small and widely varying numbers, such as the numbers of patients trained for home hemodialysis and peritoneal dialysis, both methods tend to return regression equations with very small R^2 values, indicating that neither method returns a particularly reliable result.

For this project, the best fit utilization projections for King County were prepared using linear estimates for the number of dialyses and the number of patients trained for home hemodialysis, and non-linear estimates for the number of patients and the number of patients trained for peritoneal dialysis. Results of the department's "best fit" projections are shown in Table I below: [source: Department's methodology based on NRN facility utilization data]

Table I
Department's Dialysis Station Projections
for King County Based on 2000-2004 Historical Data

Year	Stations	Existing Capacity	Net Need
2005	260	(subtract)) 290[5]	-30
2006	269		-21
2007	278		-12
2008	286		-4
2009	295		5

[5] Federal Way Community Dialysis Center (15); NKC Auburn Kidney Center (24); NKC Cascade Kidney Center (12); NKC Elliott Bay Kidney Center (18); NKC Haviland Kidney Center (53); NKC Lake Washington Kidney Center (18); NKC Lake City Kidney Center (13); NKC Mt. Rainier Kidney Center (22); NKC Scribner Kidney Center (22); NKC Snoqualmie Ridge Kidney Center (9) NKC Totem Lake Kidney Center (15); NKC West Seattle Kidney Center (20); Olympic View Dialysis Center (20); Kent Community Dialysis Center (12); Bellevue Dialysis Center (10); and West Seattle Dialysis Center (7).

As shown in Table I above, the department projects a surplus of 21 dialysis stations in King County for year 2006, decreasing to a net need for 5 stations by the end of year 2009.

Using the department's methodology as a starting point and patient origin information for years 2000-2004, NKC also projected a need for stations in King County, which is shown in Table II below: [source: Application, Appendix 17]

Table II
Applicant's Dialysis Station Projections
for King County Based on 2000-2004 Historical Data

Year	Stations	Existing Capacity	Net Need
2005	269	(subtract)) 290[6]	-21
2006	281		-9
2007	295		5
2008	308		18

As shown in Table II above, the applicant projects no net station need in the county until year 2007, which is two years earlier than the department's projections shown in Table I. The applicant projects a 5 station need by the end of year 2007, and 18 station need by the end of year 2008. When comparing the applicant's projections in Table II and the department's projections in Table I, the department concludes that the difference in net need may be attributed to two issues: different data for numbers of patients trained for home hemodialysis and peritoneal dialysis; and application of the numeric methodology. The number of training patients in King County used by the applicant does not match the numbers in the department's records. It also appears that the applicant's non-linear estimates for number of treatments and number of patients were prepared using only four years' data, rather than five.

The department and the applicant agree that there is a need for additional stations in King County, although they differ on what year that need presents itself. Relying on the most recent historical data, 2000-2004, and then subtracting the most current number of existing stations (290), the department's application of the methodology results in a net need of 5 dialysis stations in year 2009 for King County, as shown in Table I.

In previous dialysis applications proposing to serve King County, the department has further refined the service area based on documents provided in the application. For this project, NKC identified the sub-service area as ten zip codes in southeast King County[7] and noted that there is one other similar provider in the service area – Kent Community Dialysis Center, operated by DaVita, Inc. [source: Application, pp7-8]

NKC offered a further refinement of its proposed service area to be a subset of the southeast King County area, described as the "Renton Service Area." [source: application, appendix 18]

[6] Federal Way Community Dialysis Center (15); NKC Auburn Kidney Center (24); NKC Cascade Kidney Center (12); NKC Elliott Bay Kidney Center (18); NKC Haviland Kidney Center (53); NKC Lake Washington Kidney Center (18); NKC Lake City Kidney Center (13); NKC Mt. Rainier Kidney Center (22); NKC Scribner Kidney Center (22); NKC Snoqualmie Ridge Kidney Center (9) NKC Totem Lake Kidney Center (15); NKC West Seattle Kidney Center (20); Olympic View Dialysis Center (20); Kent Community Dialysis Center (12); Bellevue Dialysis Center (10); and West Seattle Dialysis Center (7).
[7] 98030, 98031, 98032, 98055, 98053, 98057, 98058, 98064, and 98178.

NKC's self-described Renton service area is composed of six of the ten southeast King County zip codes previously identified in the application. NKC explains this refinement by stating,

> *"Although the NKC-Mount Rainier Kidney Center's historical primary service area includes the Kent community, and it continues to serve patients referred from that area, this projection of station need specifically excludes patients who reside in zip codes in the Kent community because there is an existing dialysis facility in that community."* [source: application, p21]

To assist in its evaluation of this sub-criterion, the department obtained patient origin zip code data from DaVita for its two facilities nearest to the sub-service area and patient origin zip code data from NKC as provided in recent CN applications. [source: NKC October 28, 2004, supplemental information supporting its application to add additional stations to NKC-Auburn Kidney Center, and DaVita's October 19, 2005, responses to the department's specific request for patient origin zip code data] A review of that data follows:

DaVita's Kent Community Dialysis Center (KCDC)

This center is located at 21501 – 84th Avenue South in the city of Kent. It is approximately 2 miles from MRKC. KCDC has been in operation since 1999 with 12 in-center stations. When the KCDC proposal was reviewed in 1998, NKC's Mt Rainier Kidney Center was determined to be in the same service area as KCDC. For year end 2004, DaVita reported KCDC served a total of 42 patients. KCDC's zip code origin data reveals that patients residing in the zip codes designated by NKC as southeast King make up 55% of its total patient base, and those residing in the NKC-designated Renton subset of the Southeast King area make up 17% of KCDC's total patient base. For the most recent quarter available when DaVita submitted its response, the quarter ending June 30, 2005, those percentages were 58% and 20%, respectively.

DaVita's Bellevue Dialysis Center (BDC)

This center is located at 3535 Factoria Boulevard Southeast in the city of Bellevue. It is approximately 11 miles from MRKC. BDC has been in operation since 2004 with 10 in-center stations. In its initial CN application, BDC identified MRKC as a facility not located in its proposed service area, but serving patients residing in some of the same zip codes. In that evaluation process, the department concluded that MRKC and BDC were not in the same service area. For year end 2004, DaVita reported BDC served a total of 9 patients. BDC's zip code origin data reveals that patients residing in the zip codes designated by NKC as southeast King make up 11% of its total patient base, and those residing in the NKC-designated Renton subset of the Southeast King area make up none of BDC's total patient base. For the most recent quarter available when DaVita submitted its response, the quarter ending June 30, 2005, those percentages were 15% and 8%, respectively.

NKC's Auburn Kidney Center (AKC)

This 24-station facility is located at 1501 West Valley Highway North, #104 in the city of Auburn. It is approximately 9 miles from MRKC. In its review of AKC's recent CN application to add additional dialysis stations, the department concluded that AKC and MRKC were not in the same service area. For year end 2003, NKC reported AKC served a

total of 96 patients. AKC's zip code origin data reveals that patients residing in zip codes designated by NKC as southeast King make up 18% of its total patient base, and those residing in the NKC-designated Renton subset of the Southeast King area make up 1% of AKC's total patient base. For the most recent quarter available when NKC provided this information, the quarter ending June 30, 2004, those percentages were 18% and 2%, respectively.

In addition to the patient origin zip code data provided by DaVita, both entities provided comments for consideration on whether MRKC and any other facilities are in the same sub-service area and whether other centers should be considered when evaluating this sub-criterion.

DaVita, Inc. [source: DaVita's October 24, 2005, comments, pp1-2]
"DaVita does not agree that any zip code overlap, no matter how trivial, indicates facilities in the same market area. DaVita also does not agree that patient residence proximity alone indicates facility selection. Nevertheless, if the Program intends to apply that standard, it should do so consistently. Having concluded that zip code overlap could put Mt. Rainier and Auburn Kidney Center in the same service area, then it should follow that Auburn would stand to lose market share to Mt. Rainier if the application is approved. Any loss of patients from Auburn to Mt. Rainier would reduce Auburn's market share in relation to Mt. Rainier and other facilities located in south King County--Kent Community Dialysis Center, Federal Way Dialysis Center and potentially NKC's application cannot satisfy the need criteria of WAC 246-310-280(4) under the Program's current interpretation and the application must be denied.

"The market share impact rule is not limited to facilities in the same service area. Rather, it looks to any facility that "stands to lose market share," regardless of location. The Program has previously acknowledged that DaVita's Bellevue Dialysis Center ("BDC") serves patients who reside in zip codes served by Mt. Rainier. Applying the assumption used by the Program in its recent Tacoma decision that patients residing in overlapping zip codes would transfer to a closer new facility, BDC stands to lose market share to Mt. Rainier. For this reason, the Mt. Rainier application fails the market share impact criteria and its application should be denied. Expansion of the Mt. Rainier facility would draw actual or potential patients from BDC, prolonging that facility's already too protracted climb toward efficient utilization levels."

NKC [source: NKC November 7, 2005 rebuttal, pp1-2]
"We disagree with the core premise of this argument. In the analysis of the Certificate of Need application to expand the NKC-Auburn Kidney Center, the Department concluded:

"…As a side note, the GIS data also indicated that both Cascade Kidney Center and Mt. Rainier Kidney Center could be included in the south King County service area, however, past CN evaluations demonstrate that neither of those facilities have historically been included in the same service area with the Auburn, Kent, or Federal Way facilities. Therefore, they will not be included in this evaluation."

"The same statement has been included in other recent Department Certificate of Need Evaluations involving Auburn, Kent and Federal Way facilities. We agree with the Department's consistent conclusion that the communities of Renton and Auburn have not been, and should not be, incuded in the same service area. Consequently, expansion of the NKC-Mount Rainier Kidney Center in Renton will not result in a loss of market share to the NKC-Auburn Kidney Center in Auburn. Furthermore, the practical service areas of these two facilities do not even abut each other; they are separated by the community of Kent, which is currently served by the DaVita Kent Community Dialysis Center. The DaVita Kent Community Dialysis Center, geographically located between the NKC-Mount Rainier Kidney Center and the NKC-Auburn Kidney Center, effectively protects the NKC-Auburn Kidney Center market share from the NKC-Mt. Rainier Kidney Center."

On the basis of the patient data discussed above, and representations made by both NKC and DaVita, the department concludes that the service areas for all four facilities overlap. A review of the year end patient origin zip code data shows that while there is an overlap, it is not an unusual overlap for the three facilities considering their locations in relation to each other. The department concludes that MRKC and KCDC share a service area, while BDC and AKC occupy service areas that abut MRKC's service area.

Applying the methodology found in WAC 246-310-280, the department projects the need for dialysis stations to be needed in the sub-service area described in Appendix 4 of the application. The projections are shown in Table III below: [source: Department's methodology based on Northwest Renal Network facility utilization data]

Table III
Department's Dialysis Station Projections
for Southeast King County Based on 2000-2004 Historical Data

Year	Total Stations Needed	Existing Capacity	Net Need
2005	39	(subtract) 34[8]	5
2006	42		8
2007	46		12
2008	49		15
2009	52		18

As shown in Table III above, subtracting the existing number of dialysis stations located in the sub service area from the projected number of stations yields a net need of 5 stations in year 2005, which increases to 18 stations by the end of year 2009.

In summary, when comparing the results of Tables I, II, and III, above, the department concludes that there is a need for additional dialysis stations in King County as shown in Table I, and a need for additional stations in the sub-service area of southeast King County as shown in Table III.

[8] NKC Mt. Rainier Kidney Center (22) and DaVita Kent Community Dialysis Center (12).

WAC 246-310-280(4) requires that the existing dialysis centers that would stand to lose market share by approval of a project, must be operating at or above 80% capacity before additional stations may be added. While the department determined that KCDC is the only other facility in the applicant's sub-service area of southeast King County, the department notes that on the basis of patient origin information there are two dialysis facilities in addition to KCDC that serve some of the patients residing in this planning area – NKC-Auburn Kidney Center (AKC) and DaVita Bellevue Dialysis Center (BDC). In a recent ruling regarding the appeal of the award of a certificate of need, the department's health law judge concluded, "…WAC 246-310-280(4) anticipates the consideration of facilities which are outside of the defined service area when determining whether an application complies with the 80% utilization requirement." In that case, MRKC was one of the facilities identified by the health law judge as potentially losing market share by establishment of BDC. Despite NKC's assertions in its rebuttal documents that neither AKC nor BDC stand to lose market share by expansion of MRKC, the data discussed above indicate that both those facilities serve patients from MRKC's defined service area and would, therefore, stand to lose market share if MRKC's expansion attracted those patients from AKC and BDC.

Year end 2004 NRN data reveals that KCDC was operating at 64% capacity, AKC was operating at 93% capacity, and BDC was operating at 10.4% capacity. To further evaluate this sub-criterion related to BDC, AKC and KCDC, the department also reviewed unverified March, June, and September 2005 quarterly data.[9] A summary of that review is shown in Table IV below:

Table IV
Department's Review of Quarterly Utilization Data

	12/2004*	03/2005**	06/2005**	09/2005**
MRKC	92.1%	94.7%	97.7%	92.3%
KCDC	64.4%	88.9%	93.1%	108.3%
AKC* **	93.0%	94.1%	66.7%	54.2%
BDC	10.4%	20%	23.3%	20%

*calculated by dividing total number of dialyses performed in 2004 by the product of the number of approved stations multiplied by 936
**calculated by multiplying number of patients by 156, then dividing that number by the product of the number of approved stations multiplied by 936
***Prior to 05/17/05, approved stations totaled 17. Following 05/17/05, approved stations totaled 24

As noted in Table IV above, based on the most recent quarterly data (March 2005), both AKC and BDC are operating below 80% utilization. The department notes that, effective July 24, 2005, four dialysis stations and an undisclosed number of patients were transferred from AKC to MRKC to accommodate the construction required to build-out AKC's total of 24 approved stations. As a result, the September 2005 utilization reflects only 13 operational stations of the total of 24 approved stations. Similarly, the September 2005 utilization at MRKC reflects utilization of 26 stations, rather than the facility's typical 22 approved

[9] As of the writing of this evaluation, verified 2004 data has not yet been released by NRN; however, according to a representative from NRN, the changes or corrections resulting from the data verification process is minimal.

stations. Documents provided to the department by NKC indicate that this temporary transfer of stations and patients ended December 19, 2005.

Because of the intermingling of MRKC and AKC patients during the renovation and expansion of AKC, the department is unable to evaluate whether AKC truly stands to lose market share by addition of stations to MRKC. The department does, however, conclude that because MRKC and BDC both draw patients from some of the same zip codes, geographically located between MRKC and BDC, BDC stands to lose market share by addition of stations to MRKC. As Table IV indicates, BDC is operating below 80% utilization in each of the most recent reporting periods.

Based on the above data, this standard is not met.

The department must also evaluate whether MRKC would project to be operating at 80% capacity (748.8 dialyses per non-training station) by the end of year three (WAC 246-310-280(5)). As stated in the project description portion of this evaluation, if this project is approved, NKC anticipates commencement of this project shortly after CN approval and completion by June 30, 2006. The first full year of operation as a 28-station facility is the fiscal year 2006-2007. [source: Application, p17] NKC provided its projected utilization as a 28 station facility to be 83% in year 2007, 87% in year 2008, and 91% in 2009. [source: Application, Appendix 11] As a result, MRKC would meet this sub-criterion by the end of year three; and this standard is met.

Based upon the above information, the department concludes that this sub-criterion is met.

(2) <u>All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.</u>

All residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently have access to services at MRKC. The addition of stations to the dialysis center is not expected to change this access.

The applicant states that "no person has been or ever will be denied services by NKC or any of its facilities or programs for reasons of race, color, ethnic origin, religious belief, sex, age or lack of ability to pay." [source: Application, p23] To further assure accessibility to dialysis services, the applicant submitted the charity care policy and admission criteria, both of which substantiates that treatments will be provided to all persons referred to AKC. [source: Application, Appendices 20 and 21]

Based upon the above information, the department concludes that all residents of the service area would continue to have adequate access to the health services at MRKC. This sub-criterion is met.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicant has met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

As stated in the project description portion of this evaluation, if this project is approved, NKC anticipates completion by June 30, 2006. Based on this timeline, a fiscal year ending June 30, 2007, would be the first full year of operation as a 28-station facility. Using the financial information provided in the application, Table V below illustrates the projected revenue, expenses, and net income for fiscal years 2007-2009: [source: Application, Appendix 11]

Table V
Mt. Rainier Kidney Center Projected Revenue and Expenses Full Years 2007 - 2009

	Year One (2007)	Year Two (2008)	Year Three (2009)
# of stations	28	28	28
# of Treatments	21,840	22,776	23,868
# of Patients	140	146	153
Net Patient Revenue*	$ 5,128,250	$ 5,348,033	$ 5,604,445
Total Operating Expense**	$ 5,045,013	$ 5,249,548	$ 5,488,171
Net Profit or (Loss)	$ 83,237	$ 98,485	$ 116,274
Net Patient Revenue per Treatment	$ 234.81	$ 234.81	$ 234.81
Total Operating Exp. per Treatment	$ 231.00	$ 230.49	$ 229.94
Net Profit per Treatment	$ 3.81	$ 4.32	$ 4.87

*Includes deductions for bad debt, charity care, and contractual allowances
**Includes overhead expense

As shown in Table V on the previous page, at the projected volumes identified in the application, MRKC would be operating at a profit as a 28-station facility for the three years following completion of the project.

Based on the above information, the department concludes that the project's revenues are reasonable and this sub-criterion is met.

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

The applicant states that "The majority of reimbursements for dialysis services flow from Medicare ESRD entitlements, which are not subjected to, or affected by, capital improvements and expenditures by providers. [source: Application, p24] To evaluate whether the proposed expenditures would impact charges for services, the department reviewed the sources of NKC's patient revenue shown in the chart on the following page:

Source of Revenue	Percentage of Revenue
Medicare	74
State (Medicaid)	7
Blue Cross	2
Group Health	1
Other Insurance	15
Private Pay	1
Total	**100%**

[source: Application, p16]

As shown in the chart above, the Medicare and State (Medicaid) entitlements equal 81% of the revenue at MRKC. The department concludes that the majority of revenue is dependent upon entitlement sources which are not cost based reimbursement. Therefore, approval of this project is not expected to have an unreasonable impact on charges for services.

The cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable. This sub-criterion is met.

(3) The project can be appropriately financed.

The estimated capital expenditure for adding six stations to MRKC is $74,926. [source: Application, p13] The construction required by this project is the interior build-out necessary to accommodate the additional stations.

The source of financing for the project will be from NKC cash reserves. [source: Application, p16] A review of NKC's historical financial statements shows the funds necessary to finance the project are available.

Based on the information provided, the department concludes the expansion of MRKC would not adversely affect the financial stability of the facility or NKC. This sub-criterion is met

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicant has not met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

When this application was submitted, NKC employed approximately 150 registered nurses, 15 licensed practical nurses, and 150 dialysis technicians to staff its 12 dialysis facilities in King and Clallam counties. [source: Application, p26] Currently, MRKC employs 34.81 FTEs to staff the 22-station facility. To implement this project, NKC proposes to add approximately two FTEs each year based on the projected number of patients in those years. The current FTEs at AKC and the proposed increases for years 2006 - 2008 are shown in Table VI on the following page. [source: NKC August 19, 2005, supplemental information, p5]

Table VI
Mt. Rainier Kidney Center Current and Projected FTEs

Staff	Current FTEs	Year 2006 Increase	Year 2007 Increase	Year 2008 Increase	Total FTEs
RNs	10.18	0.55	0.48	0.55	11.76
HD Tech	21.63	1.18	1.01	1.18	25.00
Dietitian	1.00	0.25	0	0	1.25
Social Worker	1.00	0.25	0	0	1.25
Administrator	0	0	0	0	0
Other (clerical)	1.00	0	0	0	1.00
Total FTE's	**34.81**	**2.23**	**1.49**	**1.73**	**40.26**

As shown in Table VI above, NKC expects a minimal increase in FTEs for the six additional stations at MRKC. The staffing at NKC facilities is sufficient, as NKC states that they have not had to refuse admission to new patients due to staffing shortages, nor do they anticipate difficulties in neither availability nor recruitment of qualified staff. [source: Application, p26] Based on this information, the department concludes that adequate staffing for the additional stations at MRKC is either available or can be recruited, and this sub-criterion is met.

(2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.
Documentation provided in the application confirms that AKC currently has appropriate relationships with ancillary and support services. Ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, plant operations, and administration and technical services are provided either through NKC's Haviland facility in the central Seattle area or its Lake City facility located in north Seattle area. [source: Application, p27] Further, NKC has an umbrella hospitalization transfer agreement with Swedish Medical Center in Seattle that incorporates all NKC patients and programs by specific reference. [source: Historical CN files, and NKC responses to screening questions, p6]

Based on this information, the department concludes that both NKC, and specifically MRKC, currently have appropriate relationships with ancillary and support services and approval of this project would not negatively affect those relationships. This sub-criterion is met.

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.
NKC currently operates a total of 12 facilities in King and Clallam counties and has been operating dialysis centers since 1962 with the opening of its Haviland facility in central Seattle. In the most recent 10 years, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 45 compliance surveys for the NKC facilities in operation, which includes five surveys for MRKC, which was established in 1986. All compliance surveys revealed minor non-compliance issues related to the care and management at the NKC facilities. These non-compliance issues were typical of a dialysis

facility and NKC submitted an acceptable plan of corrections. [source: facility ownership and survey data provided by the Office of Health Care Survey]

Currently, Vilma Quijada, MD is the medical director at MRKC. A review of Dr. Quijada's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [source: Application, Supplement 2; compliance history provided by Medical Quality Assurance Commission]

Based on NKC's compliance history and the compliance history of the medical director, the department concludes that there is reasonable assurance that the MRKC would continue to operate in conformance with state and federal regulations with the additional stations. This sub-criterion is met.

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

To demonstrate that this project will promote continuity of care, the applicant provided the following statements:

> "The NKC-Mount Rainier Kidney Center has been providing outpatient dialysis services to the communities in and around Renton since 1986. The additional capacity will allow that commitment to the community to continue and will prevent the situation in which served persons must leave their community to seek care elsewhere." [source: Application, p27]

In the need section of this evaluation, the department noted that BDC, a facility operating below 80% utilization, stands to lose market share by expansion of MRKC, thus resulting in unwarranted fragmentation of services. This sub-criterion is not met.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This sub-criterion is addressed in sub-section (3) above.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicant has not met the cost containment criteria in WAC 246-310-240.

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

NKC considered and rejected the following seven alternatives before submitting this application. [source: Application, pp28-29]

a) Postponement:

This option requires new patients in the sub-service area travel outside their community to access dialysis services. NKC rejected this option because it is inconsistent with its

goals to continuously seek opportunities to improve convenience and access to care for patients

b) Night Time Services:
This option requires NKC to offer and staff a fourth shift, from 11:00pm to 7:00 am. Outpatient dialysis requires 3 to 5 hours of treatment three times a week, therefore, most patients and their physicians did not support this option because it is not only inconvenient for the patient, it is difficult to staff a center during these hours of operation.

c) Shortened Treatment Times:
Additional treatment capacity may be achieved by simply shortening the existing treatment times for each patient in order to accommodate four patient shifts per day, rather than the standard of three. This concept is not medically indicated because medical evidence suggests that longer, rather than shorter, dialysis times result in better overall care and outcomes for patients. As a result, the average treatment times at the NKC facilities have been increasing, not decreasing.

d) Home dialysis:
This option was rejected because home dialysis only appeals to 10-15% of all patients. In-center stations are still needed to accommodate the remaining 85-90% of the patients.

e) Daily dialysis:
NKC states it operates the largest home daily dialysis program in this area of the country. As of August 31, 2004, NKC has 21 home hemodialysis patients undergoing daily dialysis using the innovative Aksys personal hemodialysis (PHD) system. However, as with other forms of home dialysis therapy, this appeals to a limited number of patients, and NKC does not expect the census in the program to rise significantly in the near future.

f) Kidney transplantation:
NKC advocates for kidney transplantation for patients who qualify. Currently 40% of NKC's patients have placed their names on the organ waiting list at one or more of the three kidney transplant centers in Seattle. However, the supply of donor organs does not keep up with the demand, therefore, this is not an option for many dialysis patients

g) Shared/Contract service agreements:
NKC states that the only other dialysis provider in the primary service area of AKC is [DaVita's] Kent Community Dialysis Center which is also nearly full and would be unable to accommodate new patient referrals from the Auburn vicinity.

In the need portion of the evaluation, the department concluded that an existing facility, Bellevue Dialysis Center, stands to lose market share by implementation of this project. That facility is operating below 80% utilization. As a consequence the department concludes that adding stations to MRKC is not the best alternative at this time, and this sub-criterion is not met.